NATIONAL LATINA INSTITUTE FOR REPRODUCTIVE HEALTH

October 13, 2005

Re: Docket No. 2005N-0345

Dear Acting Commissioner von Eschenbach,

I am writing to you on behalf of the National Latina Institute for Reproductive Health (NLIRH) in response to the Advance Notice for Proposed Rulemaking, Docket Number 2005N-0345. NLIRH is a non-profit organization based in New York dedicated to ensuring the fundamental human right to reproductive health care for Latinas, their families and their communities. We strongly urge you to suspend the rule-making process and make emergency contraception (EC) available over-the-counter (OTC) effective immediately. We are outraged that the FDA has continued to ignore medical and scientific consensus and deny Latinas of all ages OTC access to this important birth control option.

As you know, EC has been proven to be a safe, reliable and responsible means of preventing pregnancy after unprotected sex or contraceptive failure. It is estimated that widespread use could prevent as many as half of the three million unintended pregnancies each year, many of which end in abortion. If taken within 72 hours of intercourse, EC can reduce the risk of pregnancy by as much as 89 percent.

Latinas have high rates of contraceptive failure, unintended pregnancy and abortion, as well as the highest teen birth rate of any racial or ethnic group. We believe that the availability of over-the-counter EC could play a dramatically important role in reducing these rates among Latinas. Moreover, almost 40% of Latinas are uninsured and face significant barriers to accessing health care providers. The fact that EC requires a prescription prevents many Latinas from accessing this important source of contraception. Latinas are a key constituency whose reproductive options could be greatly improved by the provision of over-the-counter EC.

The FDA has claimed that there is not enough data on how the drug will be used by young girls if it becomes available over-the-counter. However, the FDA has ignored research that demonstrates the benefits that over-the-counter EC would have for many uninsured, low-income young women, especially Latinas. Moreover, volumes of scientific data and medical consensus show that women of all ages can use Plan B safely and effectively without a prescription and there is no support for the concern about increasing promiscuity among adolescents.

It has been almost two years since the FDA first received the OTC application for Plan B. Despite the evidence and an overwhelming scientific and medical consensus, the agency has continued to find ways to deny or delay access to over-the-counter EC. We believe

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the proposed rule-making process is another unnecessary and unwarranted mechanism that politicizes a scientific inquiry. The rulemaking process also undermines the credibility and legal duty of the FDA to act on the scientific evidence and promote public health. There is absolutely no justification for denying women over-the-counter access to this safe and effective method of contraception.

As the Acting Commissioner of the FDA, we are calling on you to do the right thing and approve the application to make Plan B available over-the counter without further delay.

Sincerely,

Silvia Henriquez
Executive Director